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09/876,235	06/06/2001	Jack W. Szostak	00786/350009	6199

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,235

Applicant(s)

SZOSTAK ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-79 is/are rejected.
- 7) ☒ Claim(s) 77 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 19 December 2005 in which claim 63 was amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 21 June 2005 under 35 U.S.C. 112, first paragraph and under obviousness-type double patenting are maintained. The previous rejections under 35 U.S.C. 102(e) are withdrawn in view of the amendments. Applicant's arguments regarding Gold et al have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 63-79 are under prosecution.

Claim Rejections - 35 USC § 112: Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to puromycin-like compounds and adenine-like compounds. However, the specification does not provide an adequate written description of the claimed invention. The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol. 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Reduction to practice

The specification does not describe an actual reduction to practice of the claimed invention. The specification defines peptide acceptors in the paragraph spanning pages 20-21 as being a puromycin, puromycin-like, adenine, or adenine-like compound. The specification further provides specific examples of compounds having properties similar to puromycin and/or adenine. However, the specification does not reduce to practice the broadly claimed puromycin-like and/or adenine-like compounds.

Completed by drawings

The specification does not illustrate the broadly claimed puromycin-like and/or adenine-like compounds.

Description of identifying characteristics

The specification has not been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention. The specification defines properties of peptide acceptors in the paragraph spanning pages 20-21. However, the specification does not teach or describe identifying characteristics which show that applicant was in possession of the claimed puromycin-like and/or adenine-like compounds.

For the above reasons, the specification does not provide a written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude the inventor had possession of the claimed invention see *In re Vas-Cath, Inc.* 935F2d. 1555, 1563, 19 USPQ2d 1111,1116

Response to Arguments

5. Applicant asserts that the MPEP § 2163 provides that subject matter need not be described literally to satisfy the requirement under written description. Applicant's assertion is noted, but is not persuasive to overcome the above rejection. The claims are drawn to a genus i.e. puromycin-like and adenine-like. The courts have stated that disclosure of claims drawn to a genus must be described by representative number of species so as to indicate that Applicant has invented the claimed genus.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee

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of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). “A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.” In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.)(MPEP § 2163 (3) ii).

The specification does not describe a representative number of species encompassed by the claimed genus. The specification does not describe how “like” modifies the puromycin or adenine. The specification does not describe whether the claimed compounds are like puromycin or adenine in function and/or structure and/or other physical or chemical property. In contrast, the specification teaches that the claimed genus is very, very large.

Other possible choices for acceptors include tRNA-like structures at the 3' end of the mRNA, as well as other compounds that act in a manner similar to puromycin. Such **compounds include, without limitation, any compound which possesses an amino acid linked to an adenine or an adenine-like compound**, such as the amino acid nucleotides, phenylalanyl-adenosine (A-Phe), tyrosyl adenosine (A-Tyr), and alanyl adenosine (A-Ala), as well as amide-linked structures, such as phenylalanyl 3' deoxy 3' amino adenosine, alanyl 3' deoxy 3' amino adenosine, and tyrosyl 3' deoxy 3' amino adenosine; in any of these compounds, any of the naturally-occurring L-amino acids or their analogs may be utilized. In addition, a combined tRNA-like 3' structure-puromycin conjugate may also be used in the invention.

Furthermore, Applicant has not provided any evidence that the terms puromycin-like or adenine-like are well known in the art so as to illustrate that one of skill in the art would be appraised of the meets and bounds of the claimed compounds.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 63-64, 68-76 and 78-79 are rejected under 35 U.S.C. 102(e) as anticipated by Gold et al (U.S. Patent No. 5,843,701, filed 31 January 1992).

Regarding Claim 63, Gold et al disclose a molecule comprising a nucleic acid portion and a protein portion covalently bound to the nucleic acid portion through a peptide acceptor wherein said protein portion is encoded by the nucleic acid portion (e.g. attaching biotin to the mRNA and translating an avidin peptide sequence wherein biotin-avidin forms a covalent bond between the mRNA and peptide (Column 21, lines 47-Column 22, line 17). Gold et al further teach that the peptide is covalently linked to either end of the mRNA (Column 21, lines 10-15).

Regarding Claim 64, Gold et al disclose the molecule wherein the protein portion comprises two or more amino acids joined by peptide bonds i.e. polypeptide (Column 7, line 64-Column 8, line 15).

Regarding Claim 68, Gold et al disclose a method for in vitro selection and evolution comprising constructing the molecules of Claim 63 (Column 22, lines 18-67) selecting one or more of the molecules and using the nucleic acid of the molecules mutagenically construct a second plurality of molecules (Example 6).

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Regarding Claim 69, Gold et al disclose the method further comprising selecting one of the second plurality which are different from the first selected molecules i.e. selection following multiple rounds of SPERT (Example 6).

Regarding Claim 70, Gold et al disclose the method wherein the selecting comprises contacting the first plurality of molecules with a target molecule (e.g. gut membrane molecules, Example 6, Column 34, lines 49-51).

Regarding Claim 71, Gold et al disclose the method wherein the selecting comprises contacting the first and second plurality of molecules with a target molecule (e.g. gut membrane molecules and multiple rounds of SPERT, Example 6, Column 34, line 61-Column 35, line 5).

Regarding Claim 72, Gold et al disclose the method using mutagenic PCR (Column 34, lines 65-67).

Regarding Claim 73, Gold et al disclose a method for assaying protein/protein or protein/nucleic acid interaction, the method comprising constructing the molecules of Claim 63 and determining whether the molecule interacts with another protein or nucleic acid i.e. partitioning, (Column 22, lines 18-67).

Regarding Claim 74, Gold et al disclose the method wherein the determining uses an antibody (Column 26, lines 8-31 and Example 10).

Regarding Claim 75, Gold et al disclose the method wherein the determining comprises immunoprecipitation (Column 26, lines 25-27).

Regarding Claim 76, Gold et al disclose the method wherein the determining immunoprecipitation is carried out with a c-myc antibody (Column 26, lines 25-27 and Example 10).

Regarding Claim 78, Gold et al disclose the molecule of Claim 63 wherein the peptide acceptor is a puromycin-like compound i.e. tRNA 2'deoxy-3' amino-adenosine (Column 24, lines 7-10).

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Regarding Claim 79, Gold et al disclose the molecule of Claim 63 wherein the peptide acceptor is an adenine-like compound i.e. tRNA 2'deoxy-3' amino-adenosine (Column 24, lines 7-10).

8. Claims 63-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Mattheakis et al (WO 95/11922, published 4 May 1995).

Regarding Claim 63, Mattheakis et al disclose a molecule comprising a nucleic acid portion and a protein portion covalently bound to the nucleic acid portion through a peptide acceptor wherein said protein portion is encoded by the nucleic acid portion (e.g. peptide-specific antibody covalently attached to the 3' end of the mRNA (page 51, lines 22) or biotin-avidin crosslinking, (page 53, lines 1-31 and page 15, line 29-page 16, line 4).

Regarding Claim 64, Mattheakis et al disclose the molecule wherein the protein portion comprises two or more amino acids joined by peptide bonds (page 23, lines 31-38 and page 57, lines 29-33).

Regarding Claim 65, Mattheakis et al disclose a molecule comprising a nucleic acid portion and a protein portion covalently bound to the nucleic acid portion through a peptide acceptor wherein said protein portion is encoded by the nucleic acid portion (e.g. stalling codons, page 42, line 23-page 43, line 31; peptide-specific antibody covalently attached to the 3' end of the mRNA (page 51, lines 22) or biotin-avidin crosslinking, (page 53, lines 1-31 and page 15, line 29-page 16, line 4). Mattheakis et al teach the method of making the molecule comprises preparing DNA, RNA from the DNA, attaching to the 3' end of the RNA a peptide acceptor (e.g. stalling codons, page 42, line 23-page 43, line 31; peptide-specific antibody covalently attached to the 3' end of the mRNA (page 51, lines 22) or biotin-avidin crosslinking, (page 53, lines 1-31) and translating the RNA in a cell-free system (page 31, lines 26-30).

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Regarding Claim 66, Mattheakis et al disclose the method wherein step (a) comprises synthesizing a DNA primer and DNA template and amplifying the template using the primer and PCR (page 31, lines 3-18).

Regarding Claim 67, Mattheakis et al disclose the method wherein the cell-free system is wheat germ or reticulocyte (page 31, lines 26-30).

Regarding Claim 68, Mattheakis et al disclose a method for in vitro selection and evolution comprising constructing the molecules of Claim 63 (e.g. pages 71-73) selecting one or more of the molecules and using the nucleic acid of the molecules mutagenically construct a second plurality of molecules (Example 1).

Regarding Claim 69, Mattheakis et al disclose the method further comprising selecting one of the second plurality which are different from the first selected molecules (Example 1: e.g. page 66-page 72).

Regarding Claim 70, Mattheakis et al disclose the method wherein the selecting comprises contacting the first plurality of molecules with a target molecule (e.g. dynorphin B as a receptor, page 66, lines 29-38).

Regarding Claim 71, Mattheakis et al disclose the method wherein the selecting comprises contacting the first and second plurality of molecules with a target molecule (e.g. dynorphin B as a receptor, page 66, lines 29-38).

Regarding Claim 72, Mattheakis et al disclose the method using mutagenic PCR (page 18, lines 11-16).

Regarding Claim 73, Mattheakis et al disclose a method for assaying protein/protein or protein/nucleic acid interaction, the method comprising constructing the molecules of Claim 63 and determining whether the molecule interacts with another protein or nucleic acid i.e. partitioning, (Example 1: e.g. page 66-page 72).

Regarding Claim 74, Mattheakis et al disclose the method wherein the determining uses an antibody (Example 1 e.g. page 71-72).

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Regarding Claim 75, Mattheakis et al disclose the method wherein the determining comprises immunoprecipitation (Example 1 e.g. page 71-72).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al (U.S. Patent No. 5,843,701, filed 31 January 1992).

Regarding Claim 65, Gold et al disclose a molecule comprising a nucleic acid portion and a protein portion covalently bound to the nucleic acid portion through a peptide acceptor wherein said protein portion is encoded by the nucleic acid portion (e.g. attaching biotin to the mRNA and translating an avidin peptide sequence wherein biotin-avidin forms a covalent bond between the mRNA and peptide (Column 21, lines 47-Column 22, line 17). Gold et al further teach that the peptide is covalently linked to either end of the mRNA (Column 21, lines 10-15) and teach a preferred embodiment forms a covalent bond at the 3'mRNA whereby no constraints are imposed on either the peptide or mRNA (Column 24, lines 4-14). This clearly suggests that the preferred relationship between the mRNA and peptide is via a linkage at the 3' end of the mRNA. While Gold et al do not specifically teach covalent bonding of via biotin at the 3' end of the mRNA, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to position the biotin at the 3' end of the mRNA. One of ordinary skill in the art would have been motivated to do so based on the preferred

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arrangement suggested by Gold et al and for the excepted benefit of preventing constraints on the mRNA or protein as desired by Gold et al (Column 24, lines 4-14).

Regarding Claim 66, Gold et al disclose the method wherein step (a) comprises synthesizing a DNA primer and DNA template and amplifying the template using the primer and PCR (Column 15, lines 54-65; Column 30, lines 5-10; and Column 34, lines 52-54).

Regarding Claim 67, Gold et al disclose the method wherein the cell-free system is wheat germ or reticulocyte (Column 12, lines 48-54).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 65-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,258,558.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method of making and selecting nucleic acid-protein complexes. The claim sets differ in that the patent claims further define the method steps of making and selecting. The instant claim language "comprising" encompasses any addition steps in the patent claims. As such, the patent claims are deemed a species of the instantly claimed genus method.

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The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed methods are obvious in view of the patent methods.

13. Claims 63-64 and 77-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,281,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to nucleic acid-protein complexes. The claim sets merely differ in that the patent claims define the peptide acceptor and components of the encoding sequence. The instant claim language "comprising" encompasses any addition elements recited in the patent claims. As such, the patent claims are deemed a species of the instantly claimed genus method. Therefore the instantly claimed genus complexes are obvious in view of the patent species.

14. Claims 63-64 and 77-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,214,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to protein encoding RNA molecules. The claim sets differ in that the instant claims are further drawn to the encoded protein. However, the patent defines the encoding RNA as being RNA-protein fusions as instantly defined (Abstract of the '553 patent). Therefore the instantly claimed RNA-protein fusions are an obvious embodiment of the patent RNA.

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Response to Comments

15. Applicant states that terminal disclaimers to overcome the above rejections will be submitted, if necessary, upon indication of allowability. Applicant's comment is acknowledged. The rejections are maintained.

Allowable Subject Matter

16. Claim 77 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
February 28, 2006